

General Responses to EPA's Non-Directive Comment Key Issues on the Draft Baseline Ecological Risk Assessment
October 13, 2010

Issue Category	BERA Comments	General Response
Issues needing discussion with EPA		
Calculation of additive risks to fish for dietary LOE	Non-directed comment: 23	The EPA problem formulation does not call for an analysis of chemical additivity other than for dioxin-like chemicals. In resolution of directed comments (uncertainties that underestimate risk), the LWG agreed to add a discussion of this uncertainty in the uncertainty analysis but not data analyses.
Assess risk at the individual sample scale vs. 95% UCL over larger spatial extent	Non-directed comments: 17, 37, 40, 43, 85, 107, 122, 131, 149, 151, 131, 135, 149	<p>A point-by-point assessment is not appropriate for the assessment endpoints identified by EPA for the BERA.</p> <p>Consistent with the resolution to directed comments on Eco HQs\geq1, the LWG agrees to present location-specific TRV exceedances for individual samples (as was done in the draft BERA) and identify HQs\geq1 as posing potentially unacceptable risks. Also consistent with the resolution to directed comments on Eco HQs\geq1, the spatial extent, magnitude, and ecological significance of these HQs will be evaluated. The LWG understands EPA's position to be that any HQ \geq 1 at any point in the Study Area is conclusive evidence of <i>potentially</i> unacceptable risk. The LWG wants to be clear that limited spatial extent and/ or low magnitude HQs \geq 1 are not necessarily ecologically significant and that in such cases unacceptable risk is implausible.</p> <p>Regarding risks to all fish receptors from water (comment 131), the LWG contends that UCLs calculated over the home ranges presented in the draft BERA for each fish receptor are the appropriate final step in HQ analyses for identifying potentially unacceptable risks.</p>
Fish tissue TRVs Antimony, Cd, PCBs, DDX, Hg, Lindane,	Non-directed comments: 47, 110, 112, 119, 123, 124, 139, 147, 202, 203, 204, 205,	<p>Regarding comments 47, 110, 123, 139, and 202, 203, 204, TRV tables presented in draft BERA Attachment 9 include all of and only those studies with LOELs and NOELs agreed to between the LWG and EPA based on meetings and discussion to revise the EPA provided tissue TRVs. The TRVs presented in the draft BERA were derived using @Risk software and agreed species sensitivity distribution (SSD) methods. LWG will provide the output files.</p> <p>Comment 112 - It is reasonable to assume that adverse effects occurred at the highest</p>

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October 13, 2010

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		<p>tissue concentration observed during the time course of the study, especially since no adverse effects were observed at this concentration in related studies reported in the same paper.</p> <p>Comment 110 - the fish TRV reconciliation table that the LWG sent to EPA in Nov of 2008 had an EPA recommended TRV of 9 mg/kg for antimony. No changes are proposed by the LWG.</p> <p>Comments 110, 124 - As agreed to by EPA in the document entitled "EPAFishTissueTRVResponse122808" e-mailed from Eric Blischke to the LWG on 12/22/08, a literature-based LOAEL could not be derived. Therefore, BEHP concentrations were compared to the only literature-based NOAEL identified ($\geq 9.6 \mu\text{g/g ww}$). An exceedence to a NOAEL is not indicative of risk, and therefore this exceedence will not be included in Table 7-10.</p> <p>Comment 205 - As presented in draft BERA Attachment 9, the final TRV tables agreed to between the LWG and EPA, the Ramamoorthy 1985 behavioral LOAEL was rejected for inclusion in TRV derivation. The lowest LOAEL was 0.2 mg/kg ww as reported in Schimmel et al. 1977. Too few acceptable studies were available to derive a 5th or 10th percentile TRV following the EPA-LWG agreed TRV derivation methods.</p> <p>Comments 119, 147 - Several of the TRVs have significant uncertainties not specifically related to the SSD methodology. TRV uncertainties are discussed in Section 7.1.3 and summarized in Table 7-5 and 11-2. The uncertainties presented in Table 7-13 are consistent with the uncertainties raised in these earlier sections of the document.</p>
Inclusion of carp data in fish tissue residue analysis	Non-directed comments: 106, 109, 120, 197	<p>The LWG agrees to discuss the carp data for chemicals evaluated using the tissue-residue approach in the uncertainty analysis for the omnivorous fish population assessment endpoint.</p> <p>Whole-body fish tissue for carp was analyzed for dioxin-like chemicals, including PCB congener analysis, and in the draft BERA was a surrogate for other fish species for these chemicals. However, dioxins and furans (and dioxin-like PCBs) did not screen in, and</p>

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October 13, 2010

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		<p>were not further evaluated.</p> <p>For other chemicals evaluated using the tissue-residue approach, it is important to note that carp is a non-native nuisance species in the LWR and is not a receptor of concern for the ERA per EPA's problem formulation. Because of their size and unique bottom feeding they are not representative of other fish in the LWR. Sturgeon have a similar feeding mode but sturgeon tissue data are available for assessing risk to sturgeon.</p> <p>Additionally, it is important to note that the draft BERA did assess risks to piscivorous fish and wildlife from consumption of carp. Based on these factors, analysis of risk to carp is not likely to affect risk conclusions for any receptors.</p>
Use of TTC/TSC methods for dietary approach	Non-directed comments: 128, 201, 206	<p>The TTC/TSC methods used in the draft BERA result in the exact same HQs as those resulting from Equation 1 of Problem Formulation Page 40. (See Attachment A). Dietary methods for the refined screen and BERA are equivalent.</p> <p>The text and tables in the SLERA and BERA will clearly show that TTC and TSC HQs are summed.</p>
Bird dioxin TRV	Non-directed comment: 200	<p>The selected TRV was derived following the EPA-LWG agreed methods.</p> <p>No changes are proposed by the LWG in response to this comment.</p>
Inclusion of recently available osprey egg data	Non-directed comments: 49, 82, 154, 156, 163	The LWG agrees to use the newly available osprey egg data and these data will be fully characterized in the appropriate sections of the document (e.g., data, exposure assessment, and uncertainty analysis sections)
Clarifications needed	Non-directed comments: 44, 103, 71	LWG does not understand what change is being requested or needs further clarification.
Issues needing discussion with EPA only if EPA does not agree with our written response		
Use of background/upstream	Non-directed comment: 27,	After tabulation of HQs and determination of potentially unacceptable risks, risks associated with regional/upstream data will be discussed as a component of describing

General Responses to EPA's Non-Directive Comment Key Issues on the Draft Baseline Ecological Risk Assessment
October 13, 2010

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data in BERA	70, 90, 116, 117, 127	<p>the extent and magnitude of risks in the Risk Characterization section of the BERA.</p> <p>The revised BERA will further discuss upstream data elements related to uncertainty (e.g., size, numbers of samples)</p> <p>This information will be considered for COC recommendations in the Risk Management Recommendations Section.</p>
Further evaluation of lesion prevalence in fish	Non-directed comments: 63, 136	<p>The effects data available linking lesion prevalence to population level effects are sufficiently uncertain that the results of this LOE will be inconclusive regardless of the spatial scale at which data are analyzed. Therefore, results of this analysis would not affect risk conclusions.</p> <p>No changes are proposed by the LWG in response to this comment.</p>
SLERA/Refined screen process	Non-directed comments: 16, 77, 80, 81, 82, 123, 199, 201	<p>Comment 80 - All screening steps specified in the Problem Formulation except two were included. Justification for exclusion of these steps was provided in the BERA. No changes are proposed by the LWG in response to this comment.</p> <p>Comments 77, 81 and 199 - Describing differences in COPCs resulting from the stepwise refinement of the SLERA/Refined screen processes and increasing the complexity of the fish screen would not change the risk conclusions. No changes are proposed by the LWG in response to this comment.</p> <p>Comment 201 - Additional detail on dietary TTC/TSC screening process will be provided.</p> <p>Comment 123 - EPA stated in an e-mail dated September 12, 2008 that a Total DDX, rather than individual DDT congener approach should be used. Therefore, individual DDT congeners should not be retained as COPCs. Consistent with the resolution to comments 6 and 7, the LWG agrees to identify "potentially unacceptable risks" for COIs and COPCs with uncertain TRVs. Additionally, see above response to fish tissue TRVs.</p> <p>Comment 82 – This comment is addressed under osprey eggs.</p> <p>Comment 194 - Revisions to Section 5 of the BERA will be reflected in the SLERA.</p>
Dietary uncertainty	Non-directed	In cases where worst case dietary assumptions could result in a change from no HQ

General Responses to EPA's Non-Directive Comment Key Issues on the Draft Baseline Ecological Risk Assessment
October 13, 2010

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analysis	comments: 105, 146, 150, 157	exceedances to some HQ exceedances or a large change in the magnitude of exceedance, a probabilistic analysis such as that presented for mink in figure 8-4 may provide insight into risks associated with different dietary assumptions. The LWG will explore the utility of such analyses.
Downstream data	Non-directed comments: 115, 126	The LWG contends that the CDF approach provides a good and proper means of presenting downstream data relative to the Study Area data. The LWG agrees to discuss the downstream data relative to TRVs in the risk characterization and uncertainties associated with downstream data (e.g., number of samples).
Use of BSAFs/ BSARs in shore-bird risk calculations.	Non-directed comment: 158, 159, 160	<p>The FWM is used to predict tissue concentrations, so the empirical tissue concentration data were used to test model performance. We disagree that the BSAR acceptability criteria (significantly positive slope at a p of 0.05 and an r squared greater than 0.030) are too restrictive. This is a point that, if it was going to be raised, should have been raised in comments on the bioaccumulation modeling report, which was submitted to EPA on July 21, 2009.</p> <p>Where there was neither a field-collected or laboratory-exposed tissue, a dietary exposure was estimated based on a predicted tissue using a BSAR. Predicted concentrations are only presented for those chemicals where there was a relationship between sediment and tissue; therefore no predicted concentrations were provided for the dioxin/furan TEQ, total TEQ, aldrin, and sum DDE.</p> <p>No changes are proposed by the LWG in response to this comment.</p>
Fish dietary PCB and DDT TRVs	Non-directed comments: 198, 208	<p>Table 4 of the Problem Formulation states "Use the dietary evaluation for PAH and metal contaminants only because tissue residue approach is much stronger for organics and non-regulated metals." Therefore, no dietary analysis of PCBs or DDTs was conducted for fish ROCs.</p> <p>No changes are proposed by the LWG in response to this comment.</p>
Include HQs in summary tables	Non-directed comments: 20,	Regarding comment 173, additional information will be included in the tables such as 11-1 summarizing risks assessed at the scale and complexity of the assessment endpoints.

General Responses to EPA's Non-Directive Comment Key Issues on the Draft Baseline Ecological Risk Assessment
October 13, 2010

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	75, 77, 114, 173	The LWG disagrees, however, that HQs should be presented in tables showing screening calculations. The magnitude of HQs does not convey information about the magnitude of risks because it does not contain information about the dose-response relationship for the chemical-receptor pair. To show potentially very high HQs based on highly conservative screening assumptions would impart an overly conservative approximation of risks to the lay reader. Thus, HQs should only be presented for risk calculations commensurate with the scale and complexity of the assessment endpoints presented in the conceptual model.
Remove table 7-40 "effects considerations" column	Non-directed comment: 144	Table 7-40 provides a summary of effects data uncertainties presented in the effects section (Section 7.2.3) and summarized in Table 7-21. Effects uncertainties are critical to risk conclusions so summarizing these uncertainties provides critical information for risk conclusions, thus this information should be retained in Table 7-40 and Table 11-2. No changes are proposed by the LWG in response to this comment.
Issues that do not need further discussion with EPA		
Use of COCs in the FS and beyond	Directed comments: 7, 11, 179, 180, 181 Non-directed comments: 28, 34, 55, 140	These comments were resolved in LWG-EPA meetings on Directed Comments
Risk Management Recommendations	Directed comments: 5, 6, 7, 8, 9, 10, 12, 26, 90, 145, 172, 178, 181, 184	These comments were resolved in LWG-EPA meetings on Directed Comments

General Responses to EPA's Non-Directive Comment Key Issues on the Draft Baseline Ecological Risk Assessment
October 13, 2010

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	Non-directed comments: 29, 30, 34, 40, 46, 177, 183, 186,	
Eco HQs≥1	Directed comments: 7, 8, 10, 11, 12, 26, 145, 175, 178, 179, 180, 181, 184, 185 Non-directed comments: 28, 38, 55, 140, 142, 145, 148, 174, 175, 176	These comments were resolved in LWG-EPA meetings on Directed Comments
Treatment of TZW	Directed comments: 41, 61, 86, 99, 164, 165, 167, 169, 170, 171 Non-directed comments: 1, 2, 31, 42, 51, 61, 62, 92, 93, 95, 98, 137, 167	These comments were resolved in LWG-EPA meetings on Directed Comments
Uncertainties that contribute to	Directed comment: 143	These comments were resolved in LWG-EPA meetings on Directed Comments

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October 13, 2010

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underestimating risk	Non-directed comments: 14, 15, 18, 52, 113, 143,	
Use factual statements	Non-directed comment: 22	References will be added to support scientific statements.
Address uncertainty in RI dataset	Non-directed comment: 24	The LWG agrees to discuss uncertainties associated with sampling.
Use of XAD vs. peristaltic data	Non-directed comment: 132	<p>XAD collection methods were specifically used to quantify organic chemical concentrations (PAHs, BEHP, PCBs and DDX) at levels below typical detection limits.</p> <p>XAD sample collection locations were paired with a subset of peristaltic pump sample locations (so not in the same "area" but actually same locations). In many cases, the XAD samples were the only samples that were analyzed for PCBs and DDX, so they are the only representation of those COCs. In other cases where both XAD and peristaltic samples were analyzed for the same chemicals, the peristaltic sample analytes were not detected, but the XAD analytes were.</p> <p>Since risk characterization was based on detected analytes, there is typically no overlap or issue in "dropping" the peristaltic results.</p> <p>No changes are proposed by the LWG in response to this comment.</p>
Population vs. organismal evaluation	Non-directed comments: 3, 138, 141, 162	<p>It is appropriate to state the risk conclusions in terms of the assessment endpoints, which for fish (except juvenile Chinook salmon and lamprey) are populations of the receptor species. Those ROC-COPC pairs posing potentially unacceptable risks will be made consistent with resolution to HQs>1 discussed above.</p> <p>Further discussion regarding the relationship between toxicity tests, TRVs, sampling, and populations will be added.</p>
Calculation of AWQC	Non-directed	Chlordane, heptachlor, and heptachlor epoxide do not screen in as COPCs and for this

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PCB and DDT direct exposure TRVs	comments: 88, 89	<p>reason derivation of direct exposure TRVs will not result in different risk conclusions. This is because under EPA water quality criteria methods, the bioaccumulation TRVs are necessarily more conservative than the direct exposure TRVs.</p> <p>Direct exposure TRVs were derived following EPA water quality criteria methods. The LWG agrees to present all data and calculations for derivation of the PCB and DDT TRVs.</p>
Weight of evidence analysis	Non-directed comment: 13	<p>Multiple lines of evidence were used only for benthic invertebrates, fish, and osprey eggs. The relative strengths of the LOEs used to characterize risks are dependent on the specific exposure and effects data available for each COPC so a generic approach is not appropriate.</p> <p>When the different LOEs used to assess risk result in conflicting risk estimates, the LWG will discuss the relative strength of the LOEs in the risk characterization and use this information in making risk conclusions.</p>
Requests to add info/revise document that are not likely to substantially alter the outcome of the BERA	Non-directed comments: 21, 56, 64, 74, 84, 94, 107, 108	The LWG will add information/expand the discussion if it results in better readability of the documents, a more factual presentation of the issue, or clearer risk conclusions.
Benthic RA	Non-directed comments: 4, 73, 76, 83, 96, 97, 100, 101	Comments on the benthic risk assessment will be addressed in separate discussions considering EPA's comments on Section 6 of the BERA.
Agree with revision	Non-directed comments: 19, 25, 32, 33, 35, 36, 39, 45, 48,	The LWG agrees with EPA's comment and will implement as requested.

General Responses to EPA's Non-Directive Comment Key Issues on the Draft Baseline Ecological Risk Assessment
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